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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/534,098	05/06/2005	Jean-Louis Escary	21349/17	2462
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21710 7590 07/21/2006

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EXAMINER

WOODWARD, CHERIE MICHELLE

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 07/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	10/534,098		ESCARY, JEAN-LOUIS	
	Examiner		Art Unit	
	Cherie M. Woodward		1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 23-36 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 23-35, drawn to a method for providing new therapeutic agents.

Group II, claim 36, drawn to a therapeutic agent.

2. The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: claim 23 lacks novelty as being anticipated by Yue *et al.*, US Patent 6,201,106 (issued 13 March 2001, priority to 24 August 1999). Claim 23 recites a method for providing new therapeutic agents. Yue *et al.*, teach multiple human cytokine signal regulators (CKSRs), their allelic variants, including polymorphisms (column 4, lines 63-67 and column 5, lines 1-6), which meet the limitations of instant claim 23(a), claiming at least one polypeptide encoded by a natural allelic variant of one preselected gene with therapeutic potential. Yue *et al.*, teach a method of using a CKSR or fragment thereof to treat or prevent a disorder associated with increased expression or activity of CKSR (column 20, lines 65-67). Claim 23(b) requires determining the therapeutic index of the polypeptides in step (a) by three sub steps. The specification defines a therapeutic index as “generally a numerical value; it may be arbitrarily attributed by an experimenter” (specification, p. 10, lines 10-11). This is interpreted as meaning that it can be any value, real or imaginary, arbitrarily determined by any experimenter. Yue *et al.*, teach instant claim 23(b)(i), which requires the polypeptides of instant claim 23(a) to be subjected to at least two activity tests. Yue *et al.*, teach a method of assaying for the absence, presence, and excess expression of CKSR, monitoring regulation of CKSR levels during therapeutic intervention (column 27, lines 40-43), and other activity tests for CKSRs are taught at column 37, lines 62-67 to column 38, lines 1-43. Additionally, competitive drug screening assays in which neutralizing antibodies capable of

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binding CKSR compete with a test compound for binding CKSR are taught at column 31, lines 6-11. These assays meet the limitations of claim 23(b). The value of the measurements in each of the assays, as determined by the experimenter, in this case Yue et al., is sufficient to meet the criteria for claim 23(b)(ii). Applying applicant's definition of "therapeutic index" as defined in the specification, is sufficient to permit the application of values assigned by Yue et al. Yue et al., teach "standard values obtained in this manner may be compared with values obtained from samples from patients who are symptomatic for a disorder. Deviation from standard values is used to establish the presence of a disorder" (column 29, lines 12-15). The deviation of standard values, as taught by Yue et al., meets the applicant's definition of "therapeutic index" (discussed above). Yue et al., also teaches claim 23(c) at column 29, lines 17-24, as a method where the CKSRa have a new therapeutic application with respect to the CKSR (see also column 29, lines 3-23).

As such, Yue et al., teach all of the limitations of claim 23, as written. Because claim 23 is not novel, the remaining claim lacks a special technical feature. Group II does not have the same corresponding special technical feature. Restriction is required under 35 U.S.C. 121 and 372.

3. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cherie M. Woodward whose telephone number is (571) 272-3329. The examiner can normally be reached on Monday - Thursday 9:00am-7:30pm (EST).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

CMW


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